UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte FEARGHUS O'FOGHLUDHA

Appeal No. 2005-2142
Application No. 09/614,490

ON BRIEF

Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 3-9. Claims 1, 3 and 5 are representative of the subject matter on appeal, and read as follows:

1. An integral source material having at least one nuclide that is activated by exposure to radiation, the nuclide is a chemically bound constituent of the backbone of a polymer of the integral source material, wherein the integral source material is configured before activation to provide a device wherein the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy-dispersive fluorescence analysis.

3. The integral source according to claim 1, wherein the polymer is selected from the group consisting of polypropylene, polyethylene terephthalate, nylon, acrylates, polyurethane, polyphanylene oxide blends, polyphenylsulfone, polysulfone, polyether sulfone, polyphenylene sulfide, phenyletheretherketone, polyetherimide, polyphenylmetallosiloxane, fluorine containing polyphosphazines and liquid crystal polymer and blends and combinations thereof.

5. An integral source material according to Claim 1, wherein the device comprises a checkerboard comprising alternating active and inactive squares, the active squares containing the integral source material.

The examiner relies upon the following references:

Suthanthiran et al. (Suthanthiran)	5,163,896	Nov. 17, 1992
Good	5,342,283	Aug. 30, 1994
Park et al. (Park)	6,152,869	Nov. 28, 2000
Grunze et al. (Grunze)	2002/005481	May 09,2002

Claims 1, 4 and 6-9 stand rejected under 35 U.S.C. §102(b) as being anticipated by Suthanthiran, and claims 1, 3, 4 and 6-9 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Grunze. Finally, claims 1 and 3-9 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Suthanthiran or Grunze as combined with either Park or Good. After careful review of the record and consideration of the issues before us, we affirm the rejection of claims 1, 3, 4 and 6-9 under 35 U.S.C. §. 102(e) over Grunze. Because we find Grunze to be the better reference, we decline to address the merits of the rejection of claims 1, 4 and 6-9 under 35 U.S.C. §102(b) as being anticipated by Suthanthiran. Finally, we reverse the rejection of claim 5 as being rendered obvious over the combination of Grunze as combined with either Park or Good.

BACKGROUND

According to the specification,

> the present invention provides an integral source material which uses a polymer base and a nuclide or nuclides that can be activated by exposure to neutrons or other ionizing radiations in order to produce a radioactive material that is chemically integral with and is therefore not easily shed by the polymer base material and that is formable by activation by molding, casting, machining, turning, milling, drilling, grinding or other means such as laser micro-machining. The material, before activation, is formed into some desired configuration, is fabricated into medical or industrial devices and is then irradiated to make the devices radioactive. . . . The materials can be fabricated in various shapes and can be further adapted for use post-forming such as by cutting, splicing or combining with other devices.

Id. at 2. Devices that can be manufactured using the integral source material of the invention include stents, seeds, catheters and test-objects. See id. at 4. In addition, the invention materials may be used to fabricate enclosures with radioactive walls, see id. at 5, as well as shrouds, which are thin, protective layers of a polymeric substance covering the entire surface of, for example, an electronic circuit board, see id. at 7.

DISCUSSION

Claims 1, 3, 4 and 6-9 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Grunze. As the claims stand or fall together with respect to this rejection, we focus our analysis on the independent claim, i.e., claim 1.

According to the Examiner's Answer:

> Grunze discloses an integral source, i.e., an artificial implant, comprising a nuclide that is a constituent in the polymer chain (the P is in the polymer chain), such as, a fluorine containing phosphazine, see paragraphs [0013] to [0016]. For the reasons set forth above, [i.e., that in product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)] the limitation, "activated by exposure to radiation" does not differentiate over the prior art, as this [is] a step in the method of preparation. The integral source material is used in implants, stents, etc., and is contained in plastics, metals, alloys, ceramics, etc., which would be both flexible or rigid, rectangular in shape, (i.e., a stent) and since the radiolabeled polymer is used as a coating, such devices would have radioactive walls, see paragraphs [0021]-[0026]. The product of Grunze is directly within the scope of the claims, as an "activated" nuclide would be a radionuclide, which is in the polymer chain of the product of Grunze.

Examiner's Answer, page 4.

It is axiomatic that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). It is also axiomatic that the burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). We find that the examiner has met that burden, and the rejection is affirmed.

Appellant argues that "[i]n contrast to the nanometer or micrometer polymer coating proposed in Grunze, the polymer of the present invention can be configured to provide a device, such as test objects, rectangular and disc

shaped sources, radioactive enclosures, etc. That is, polymers according to the present invention can be formed into a device rather than merely being used as a coating over a device as discussed in Grunze." Appeal Brief, page 7. Appellant contends that although Grunze states that the polymers disclosed may be used as the complete material in certain applications, the examples are all drawn to coatings on the nanometer or micrometer scale. See id. In addition, appellant also asserts that "[a] coating does not 'provide a device' as recited in claim 1." Reply Brief, page 4.

Appellant's arguments are not found to be convincing. All that is required by claim 1 is that the "integral source material [be] configured before activation to provide a device wherein the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy-dispersive fluorescence analysis." Thus, although appellant asserts that the polymer of the present invention can be configured to provide a device, such as test objects, rectangular and disc shaped sources, or radioactive enclosures, the claim does not exclude a coating as taught by Grunze. That finding is supported by the teaching of the specification that the integral source material. i.e., the radioactive material, may be used as a shroud, which is defined as being a thin, protective layer of a polymeric substance. Moreover, as noted by the rejection, Grunze specifically teaches that "[t]he antithrombogenic polymer according to the invention can, however, be used not

only as a coating, but even as the complete material in particular applications, such as in their use as endovascular prostheses and the like." Grunze, paragraph [0022]. Appellant has provided no evidence that the person of ordinary skill would not know how to formulate a complete material using the radioactive polymer of Grunze given the teachings of Grunze, and arguments of counsel cannot take the place of evidence in the record. See in re Scarbrough, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); In re DeBlauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Appellant asserts further that "in contrast to the random distribution of isotopes discussed in Grunze, the present invention may reduce variations in the radioactivity because the nuclide is a chemically bound constituent of the backbone of the polymer and is activated after formation of the desired device. Accordingly, the concentration of the target nuclide in the backbone of the polymer and the resulting radioactivity post-activation can be nearly uniform." Appeal Brief, page 7 (emphasis in original).

Again, appellant's arguments are not found to be convincing. First, claim 1 does not exclude the random distribution of radionuclides along the polymer backbone. Second, Grunze teaches that every phosphorus atom in the polymer backbone may be radiolabled, see Grunze, paragraph [0013], and such a polymer would provide uniform radioactivity.

Claims 1 and 3-9 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Suthanthiran or Grunze as combined with either

Park or Good. Since we have affirmed the rejection of claims 1, 3, 4 and 6-9 under 35 U.S.C. § 102(e) as being anticipated by Grunze, we focus our analysis on the remaining claim, i.e., claim 5.

Suthanthiran and Grunze are relied upon for teaching "an integral source material comprising a nuclide, wherein the nuclide is a constituent in the polymer chain." Examiner's Answer, page 5. The examiner acknowledges that "Suthanthiran and Grunze fail to specifically disclose that the nuclide is one that is activated (e.g., made radioactive) after preparation of the source and that the source has a checkerboard form." Id.

Good and Park are relied upon for teaching the advantages of activating a nuclide by irradiation, providing both ease of preparation and safety. See id. In addition, relying on Figures 2 and 3, the examiner states that Park "teaches that the stents may be in a checkerboard." Id. The examiner concludes that "it would have been obvious to form the stents [i.e., the integral source] in a checkerboard form because the prior art teaches that this is a known and preferred means of distributing radioactive material on such stents, as shown by Park." Id. at 6.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citations omitted). The test of obviousness is "whether the teachings of

the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). In this case, we find that the examiner has not met this burden, and the rejection of claim 5 under 35 U.S.C. § 103(a) is reversed.

The examiner asserts that Figures 2 and 3 of Park show a stent, i.e., an integral source, having a radionuclide in a checkerboard design. As noted by appellant, however, in the captions to Figures 2 and 3, Park actually states that the radionuclides are distributed evenly within the polyurethane carrier. See Park, column 4, lines 28-29. Thus, contrary to the assertion in the rejection, Park does not teach that the radionuclides are distributed in a checkerboard pattern, and the rejection of claim 5 is reversed.

CONCLUSION

The rejection of claims 1, 3, 4 and 6-9 under 35 U.S.C. § 102(e) as being anticipated by Grunze is affirmed, but the rejection of claim under 35 U.S.C. § 103(a) as being obvious over the combination of Sutharian or Grunze as combined with either Park or Good is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART; REVERSED-IN-PART

Donald E. Adams)
Administrative Patent Judge)
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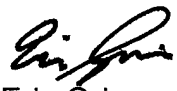
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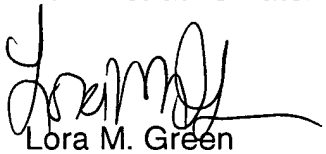
) INTERFERENCES
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